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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,778	09/21/2005	Oliver German Perez Martin	LEXSA.P32	2870
28752	7590	02/13/2008		
LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 02/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,778

Applicant(s)

PEREZ MARTIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-56 is/are rejected.
7) ☒ Claim(s) 1-4, 7-9, 12, 14, 27-30 and 56 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 04 April 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 4 April 2007, is acknowledged. Claims 1, 2, 3, 4, 7, 8, 16, 17, 18, 19, 22, 23, 27, 28, 29, 32, 33, 39, 40, 42, and 43 have been amended. New claim 56 has been added.
2. Claims 1-56 are pending and under consideration.

Objections/Rejections Withdrawn

3. The objection to Figures 2-29 for not being in English is withdrawn.
4. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claim.
5. The objection to claims 7-9, 22-24, 32-34, and 42-44 is withdrawn.
6. The rejection of claims 2-4, 27-29, and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "associated to", is withdrawn in light of the amendment of the claims.

Rejections Maintained

7. The rejection of claims 37, 38, and 53 under 35 U.S.C. 112, second paragraph, as being indefinite for "associated to", is maintained.

Applicants argue that the amendments obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because claims 37, 38, and 53 have not been amended and the phrase remains.

8. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is maintained for reasons of record.

Applicants argue that the amendments correct the informalities in accordance with the Examiner's requirements.

The examiner has considered applicants' argument, but does not find it persuasive because there is no indication of any amendment of claim 5 to correct the indefiniteness put forth in the original rejection.

9. The rejection of claims 1-55 under 35 U.S.C. 112, first paragraph, scope of enablement for a vaccine composition containing proteolipidic cochlear structures obtained from vesicles found in the outer membranes of any/all live microorganisms, is maintained.

Applicants argue that the specification clearly shows protection at prophylactic levels utilizing leishmaniasis as example, as well as induction of cellular response showing cytokine release, nitric oxide production, and IgG2a subclass production. The specification also teaches that in most vaccines, including the TB and HIV, the induction of a cellular Th1 immune response is desired. The invention is not only a vaccine composition, but also a potent vaccine adjuvant.

The examiner has considered applicants' arguments, but does not find them persuasive. As put forth in the original rejection, the claims are drawn to a vaccine composition containing proteolipidic cochlear structures obtained from the out membrane vesicles of any/all live microorganisms. The specification does provide a few examples, but insufficient for the extremely broad scope of the claims, i.e., that any microorganism can be utilized as a source for cochlear structures as vaccines. The limited number of examples does not provide enough support for the proposition that the vaccine qualities are universal, i.e., all microorganism out membrane vesicles are vaccines.

Drawings

10. Newly submitted replacement Figure 7 is objected to because in the legend "Cohleate IG" should be "Cochleate IG" and "Cohleate IN" should be "Cochleate IN".

11. Newly submitted replacement Figure 19 is objected to because in the legend "Cocheate" should be "Cochleate" and "Cocheate + Amastigotes" should be "Cochleate + Amastigotes".
12. Newly submitted replacement Figure 24 is objected to because in the legend "GRUPOS" should be "Group" and the third group "1Va+2PMV" should be "1Va+2OMV".
13. Newly submitted replacement Figure 25 is objected to because in the level of significance for day 27 has been changed from "***" to "**" denoting a change from <0.01 to <0.05 .
14. Newly submitted replacement Figure 28 is objected to because in the legend "subckasses" should be "subclasses".
15. Newly submitted replacement Figure 29 is objected to because in the legend "TITLES" should be "TITERS" and the second group "pIDKE2" should be "pIDKE".
16. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

17. The amendment filed 4 April 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: newly submitted replacement Figure 11 contains new data not presented at the time of filing.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

18. Newly amended claim 1 is objected to because of the following informalities: "membranes" should be "membrane". Appropriate correction is required.
19. Newly amended claims 2-4, 27-29 are objected to because of the following informalities: "pathogens associated" should be "pathogen associated". Appropriate correction is required.
20. Newly amended claim 7 is objected to because of the following informalities: "*neisseria haemophilus*" should be "*neisseria, haemophilus*". Appropriate correction is required.
21. Newly amended claim 8 is objected to because of the following informalities: "*streptococcus*" should be "*streptococcus*". Appropriate correction is required.
22. Claim 9 is objected to because of the following informalities: "protozoo" should be "protozoan". Appropriate correction is required.
23. Claim 12 is objected to because of the following informalities: "group consisting in:" should be "group consisting of:" and "alergenics" should be "allergens". Appropriate correction is required.

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24. Claim 14 is objected to because of the following informalities: "papilomavirus" should be "papillomavirus". Appropriate correction is required.
25. Claim 30 is objected to because of the following informalities: "strcutres" should be "structures". Appropriate correction is required.
26. Newly added claim 56 is objected to because of the following informalities: "moccroorganisms" should be "microorganisms". Appropriate correction is required.

Claim Rejections - 35 USC § 112

27. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

28. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "obtained from in the outer membranes".

29. Newly amended claims 18, 19, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether a plural or single pattern is being claimed because when the claims recite "molecular pattern are".

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30. Claims 19, 29, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "peptyglycane".

31. Claims 4, 19, 29, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by "lipophosphoglycane".

32. Claims 25, 35, 45, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "derived from" because the specification does not define the term.

33. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the phrase "and adding a non-ionic detergent is added".

34. Claims 2-4, 17-19, 27-29, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

35. Newly amended claims 2-4, 17-19, 27-29, and 39 now recite "pathogens associated molecular pattern", which applicants contend is prevalent in scientific publications and refers to

the pathogen molecules conserved during evolution which are recognized by pathogen recognition receptors and are the main target in the search for a new effective adjuvant.

36. The examiner has considered applicants' explanation, but the claimed scope of based upon the phrase remains unclear. It is unclear if the claims are drawn to all or some of such molecules, and also which molecules are identified as being encompassed by the term.

Conclusion

37. No claims are allowed.

38. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645, February 15, 2008

Application Number**Application/Control No.**

10/536,778

**Applicant(s)/Patent under
Reexamination**

PEREZ MARTIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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